



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/380,200	01/30/95	BIRNSTIEL	0652.1080001

HM12/0715  
STERNE KESSLER GOLDSTEIN & FOX  
SUITE 600  
1100 NEW YORK AVENUE NW  
WASHINGTON DC 20005-3934

EXAMINER  
CUNNINGHAM, T

ART UNIT	PAPER NUMBER
1644	37

DATE MAILED: 07/15/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/380,200

Applicant(s)

Birnstiel et al.

Examiner

Thomas Cunningham

Group Art Unit

1644

☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-33 and 35-40 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-33 and 35-40 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1644

1. This application has been transferred to a different examiner. Please direct future correspondence to Examiner Thomas Cunningham in Art Unit 1644. The **FINALITY** of the last office action is withdrawn. The amendment filed 5/16/99 has been entered. This application claims priority under 35 U.S.C. 120 to 07/946,498, filed November 9, 1992 (see Amendment F, Paper No. 16). Since this application was not pending for at least three years as of June 8, 1995 it is not eligible for transitional restriction practice under 37 C.F.R. 1.129(b). This section requires that reference be made in this application to an earlier filed application under 35 U.S.C. 120, 121 or 371.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-35 and 38-40, drawn to conjugates, complexes and preparations, classified in class 530, subclass 403.
- II. Claims 36-37, drawn to processes for introduction of nucleic acids into cells, classified in class 514, subclass 44.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product may be used in the claimed processes of introduction of nucleic acids into

Art Unit: 1644

cells or alternatively for induction of immune responses or other therapeutic, biochemical or immunological purposes.

4. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, therefore restriction for examination purposes as indicated is proper.

5. Upon election of Group I, claims 1-35 and 38-40 are generic to a plurality of disclosed patentably distinct species comprising products with structurally and functionally distinct moieties, see for example Groups I-XVII on page 12 of the Brief. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is required to specify every structural component of the elected species of complex, conjugate or preparation. An example of an electable species would be: A protein-polycation conjugate consisting of a monoclonal antibody that binds to CD4 ("the protein"), polylysine ("the polycation") and a specific nucleic acid. Applicant is further required to point out each claim which reads on the elected species.

6. Upon election of Group II, the Applicant is required to elect one ultimate species of conjugate, complex or preparation to be used in the claimed methods, see section 5 above for an example of an electable species of product.

Art Unit: 1644

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Cunningham whose telephone number is (703) 308-3968.

TC  
THOMAS M. CUNNINGHAM  
PRIMARY EXAMINER  
GROUP 1800